



ATTORNEYS AT LAW



Robert Greene Sterne
Edward J. Kessler
Jorge A. Goldstein
David K.S. Cornwell
Robert W. Esmond
Tracy-Gen G. Durkin
Michele A. Cimbara
Michael B. Ray
Robert E. Sokohl
Eric K. Steffe
Michael Q. Lee
Steven R. Ludwig
John M. Covert
Linda E. Alcorn
Robert C. Milonig
Lawrence B. Bugalsky
Donald J. Featherstone
Michael V. Messinger

Judith U. Kim
Timothy J. Shea, Jr.
Patrick E. Garrett
Jeffrey T. Helvey
Heidi L. Kraus
Albert L. Ferro*
Donald R. Banowitz
Peter A. Jackman
Teresa U. Medler
Jeffrey S. Weaver
Kendrick P. Patterson
Vincent L. Capuano
Eldora Ellison Floyd
Thomas C. Fiala
Brian J. Del Buono
Virgil Lee Beaston
Theodore A. Wood
Elizabeth J. Haanes

Joseph S. Ostroff
Frank R. Cottingham
Christine M. Lhulier
Rae Lynn P. Guest
George S. Bardmessner
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Jason D. Eisenberg
Michael D. Specht
Andrea J. Kamage
Tracy L. Muller*
Jon E. Wright
LuAnne M. DeSantis
Ann E. Summerfield
Aric W. Ledford*
Helene C. Carlson
Timothy A. Doyle*
Gaby L. Longsworth
Lori A. Gordon*

Nicole D. Dretar
Ted J. Ebersole
Jyoti C. Iyer*
Laura A. Vogel
Michael J. Mancuso
Registered Patent Agents
Karen R. Markowicz
Nancy J. Leith
Matthew J. Dowd
Aaron L. Schwartz
Katrina Fujian Pei Quach
Bryan L. Skelton
Robert A. Schwartzman
Teresa A. Colella
Jeffrey S. Lundgren
Victoria S. Rutherford
Michelle K. Holoubek

Robert H. DeSelms
Simon J. Elliott
Julie A. Heider
Mita Mukherjee
Scott M. Woodhouse
Michael G. Penn
Christopher J. Walsh

Of Counsel
Kenneth C. Bass III
Evan R. Smith
Marvin C. Guthrie

*Admitted only in Maryland
+Admitted only in Virginia
•Practice Limited to
Federal Agencies

June 8, 2005

WRITER'S DIRECT NUMBER:
(202) 772-8625
INTERNET ADDRESS:
ESTEFFE@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Art Unit 1645

Hand Carry to Examiner J.A. Hines

Re: U.S. Utility Patent Application
Application No. 10/725,009; Filed: December 2, 2003
For: **Method for Freeze-Drying Nucleic Acid/Block Copolymer/Cationic
Surfactant Complexes**
Inventors: GEALL
Our Ref: 1530.0620001/EKS/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

1. SKGF Cover Letter;
2. Information Disclosure Statement under 37 C.F.R. § 1.97(b);
3. Form PTO-1449, 5 pages, listing 51 documents (AA1-AG3, AL1-AM2 and AR1-AT5);
4. One (1) copy of the 22 cited documents (AL1-AM2 and AR1-AT5); and
5. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Commissioner for Patents
June 8, 2005
Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Eric K. Steffe
Attorney for Applicants
Registration No. 36,688

EKS/J-H/tis:awt

368358v1



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

GEALL

Appl. No.: 10/725,009

Filed: December 2, 2003

For: **Method for Freeze-Drying Nucleic Acid/Block Copolymer/Cationic Surfactant Complexes**

Confirmation No.: 3175

Art Unit: 1645

Examiner: Hines, J.A.

Atty. Docket: 1530.0620001/EKS/J-H

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents, **AL1** to **AM2** and **AR1** to **AT5** are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), copies of U.S. patents and patent application publications, documents **AA1** to **AG3**, cited on the attached Form PTO-1449 are not submitted.

The Examiner's attention is directed to the following co-pending, related applications:

U.S. Application No. 09/839,574, inventors Manthorpe *et al.*, filed April 23, 2001, now published as U.S. Publication No. 2002/0019358 A1 (Document **AI2**)

U.S. Application No. 10/360,645, inventors Wolff *et al.*, filed February 10, 2003, now published as U.S. Publication No. 2003/0186913 A1 (Document **AK2**);

U.S. Application No. 10/391,216, inventor Wheeler, C.J., filed March 19, 2003, now published as U.S. Publication No. 2003/0191082 A1 (Document **AA3**);

U.S. Application No. 10/127,683, inventors Hobart *et al.*, filed April 23, 2002, now published as U.S. Publication No. 2003/0203863 A1 (Document **AB3**);

U.S. Application No. 10/725,015, inventor Geall *et al.*, filed December 2, 2003, now published as U.S. Publication No. 2004/0162259 A1 (Document **AE3**);

U.S. Application No. 10/748,853, inventor Wheeler, C.J., filed December 30, 2003, now published as U.S. Publication No. 2004/0171572 A1 (Document **AC3**);

U.S. Application No. 10/738,986, inventors Hermanson *et al.*, filed December 19, 2003, now published as U.S. Publication No. 2004/0209241 A1 (Document **AD3**);

U.S. Application No. 09/937,604, inventor Wheeler, C.J., which is the U.S. National Phase of International Appl. No. PCT/US00/08282 (WIPO Publication No. 00/57917 A2) (Document **AN1**), having a 35 U.S.C. §371 date of September 26, 2001;

U.S. Application No. 09/478,457, inventors Wolff *et al.*, filed January 6, 2000, now pending (Document **AR5**);

U.S. Application No. 10/658,688, inventor Hermanson, G.G., filed September 10, 2003, now pending;

U.S. Application No. 10/843,656, inventors Vilalta *et al.*, filed May 12, 2004, now pending;

U.S. Application No. 11/131,479, inventors Luke *et al.*, filed May 18, 2005, now pending; and

U.S. Application No. 60/632,612, inventor Geall, filed December 3, 2004, now pending;

which are directed to related technical subject matter. Copies of co-pending U.S. Application Nos: 10/658,688, 10/843,656, 11/131,479 and 60/632,612 are not provided pursuant to the Waiver of Requirements in 37 C.F.R. § 1.98, *Official Gazette*, October 16, 2004. A copy of co-pending Application No 09/478,457 is provided as the applications are not available electronically via the United States Patent and Trademark Office Image File Wraper System (IFW). The identification of these U.S. Patent Applications is not to be construed as a waiver if secrecy as to those applications now or upon issuance of the present application as a patent.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits that document **AS4** is in a foreign language. The relevance of document **AS4** may be found in the English language abstract included therein.

The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates

should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.


Eric K. Steffe
Attorney for Applicants
Registration No. 36,688

Date: 6/8/05

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1530.0620001/EKS/JAHAPPLICATION NO.
10725,009FIRST NAMED INVENTOR
Geall, A.FILING DATE
December 2, 2003ART UNIT
1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1 5,264,618	11/23/1993	Felgner <i>et al.</i>			04/16/1991
	AB1 5,459,127	10/17/1995	Felgner <i>et al.</i>			09/16/1993
	AC1 5,567,859	10/22/1996	Emanuele <i>et al.</i>			08/09/1994
	AD1 5,656,611	08/12/1997	Kabanov <i>et al.</i>			11/18/1994
	AE1 5,691,387	11/25/1997	Emanuele <i>et al.</i>			06/03/1996
	AF1 5,696,298	12/09/1997	Emanuele <i>et al.</i>			06/02/1995
	AG1 5,817,334	10/06/1998	Schmidt <i>et al.</i>			06/06/1995
	AH1 5,990,241	11/23/1999	Emanuele <i>et al.</i>			07/08/1997
	AI1 5,994,317	11/30/1999	Wheeler			04/09/1996
	AJ1 6,251,599 B1	06/26/2001	Chen <i>et al.</i>			11/06/1998
	AK1 6,359,054 B1	03/19/2002	Lemieux <i>et al.</i>			01/08/1999

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1 WO 96/04392 A2	02/15/1996	WIPO			Yes
	AM1 WO 96/04932 A1	02/22/1996	WIPO			No
	AN1 WO 00/57917 A2	10/05/2000	WIPO			Yes
	AO1 WO 02/00844 A2	01/03/2002	WIPO			No
	AP1 WO 97/40839 A1	11/06/1997	WIPO			Yes

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	1	Corveleyn, S. and Remon, J.-P., "Maltodextrins as Lyoprotectants in the Lyophilization of a Model Protein, LDH," <i>Pharm. Res.</i> 13:146-150, Plenum Publishing Corporation (1996)
AS	1	Kim, A.I., <i>et al.</i> , "The Physical State of Mannitol after Freeze-Drying: Effects of Mannitol Concentration, Freezing Rate, and a Noncrystallizing Cosolute," <i>J. Pharm. Sci.</i> 87:931-935, American Chemical Society (1998)
AT	1	Martini, A., <i>et al.</i> , "Use of Subambient Differential Scanning Calorimetry to Monitor the Frozen-State Behavior of Blends of Excipients for Freeze-Drying," <i>PDA J. Pharm. Sci. Technol.</i> 51:62-67, Parenteral Drug Association (1997)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0620001/EKS/JAH	APPLICATION NO. 10/725,009
		FIRST NAMED INVENTOR Geall, A.	
		FILING DATE December 2, 2003	ART UNIT 1645

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2 6,482,518 B1	11/19/02	Short <i>et al.</i>			07/30/1999
	AB2 6,147,055	11/14/2000	Hobart <i>et al.</i>			03/14/1997
	AC2 5,674,911	10/07/1997	Emanuele <i>et al.</i>			06/06/1995
	AD2 6,586,409 B1	07/01/2003	Wheeler			03/24/2000
	AE2 5,703,055	12/30/1997	Felgner <i>et al.</i>			01/26/1994
	AF2 6,670,332 B1	12/30/2003	Wheeler			06/05/1998
	AG2 6,399,588 B1	06/04/2002	Hobart <i>et al.</i>			06/04/2002
	AH2 RE 36,665	04/18/2000	Emanuele <i>et al.</i>			06/02/1998
	AI2 2002/0019358 A1	02/14/2002	Manthorpe <i>et al.</i>			04/23/2001
	AJ2 2003/0032615 A1	02/13/2003	Felgner <i>et al.</i>			07/26/2002
	AK2 2003/0186913 A1	10/02/2003	Wolff <i>et al.</i>			02/10/2003

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2 WO 99/06055 A1	02/11/1999	WIPO			Yes No
	AM2 WO 99/21591 A1	05/06/1999	WIPO			Yes No
	AN					Yes No
	AO					Yes No
	AP					Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	2	Martini, A., <i>et al.</i> , "Use of subambient differential scanning calorimetry to monitor the frozen state behaviour of amino acids in simulated freeze-drying conditions," <i>S.T.P. Pharma Sci.</i> 7:37-381, Editions de sante (1997)
AS	2	Newman, M.J., <i>et al.</i> , "Use of Nonionic Block Copolymers in Vaccines and Therapeutics," in: <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , Bruck, S.D., ed., Begell House, Inc. (1998)
AT	2	Oliyai, C., <i>et al.</i> , "Chemical Pathways of Peptide Degradation. VII. Solid State Chemical Instability of an Aspartyl Residue in a Model Hexapeptide," <i>Pharm. Res.</i> 11:901-908, Plenum Press (1994)

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 <u>INFORMATION DISCLOSURE STATEMENT</u>		ATTY. DOCKET NO. 1530.0620001/EKS/JAH		APPLICATION NO. 10/725,009	
		FIRST NAMED INVENTOR Geall, A.		FILING DATE December 2, 2003	

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
AA3	2003/0191082 A1	10/09/2003	Wheeler			03/19/2003
AB3	2003/0203863 A1	10/30/2003	Hobart <i>et al.</i>			04/23/2002
AC3	2004/0171572 A1	09/02/2004	Wheeler			12/30/2003
AD3	2004/0209241 A1	10/21/2004	Hermanson <i>et al.</i>			12/19/2003
AE3	2004/0162256 A1	08/19/2004	Geall <i>et al.</i>			12/02/2003
AF3	6,867,195 B1	03/15/2005	Felgner <i>et al.</i>			06/07/1995
AG3	6,875,748 B2	04/05/2005	Manthorpe <i>et al.</i>			04/23/2001
AH						
AI						
AJ						
AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AL						Yes No
AM						Yes No
AN						Yes No
AO						Yes No
AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	<u>3</u>	Orizio, G., <i>et al.</i> , "Freeze-dried mannitol for injectable preparations using an automatic lyophilization cycle," <i>Boll. Chim. Farm.</i> 132:368-374, Societá Editoriale Farmaceutica (1993)
AS	<u>3</u>	Österberg, T., <i>et al.</i> , "Development of a Freeze-Dried Albumin-Free Formulation of Recombinant Factor VIII SQ," <i>Pharm. Res.</i> 14:892-898, Plenum Press (1997)
AT	<u>3</u>	Todd, C.W., <i>et al.</i> , "Development of an adjuvant-active nonionic block copolymer for use in oil-free subunit vaccines formulations," <i>Vaccine</i> 15:564-570, Elsevier Science Ltd. (1997)

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	4	Todd, C.W., et al., "Systemic Development of a Block Copolymer Adjuvant for Trivalent Influenza Virus Vaccine," <i>Dev. Biol. Stand.</i> 92:341-351, Karger (1998)				
AS	4	Tse, C. and Capeau, J., "Quantification des acides nucléiques par PCR quantitative en temps réel," <i>Ann. Biol. Clin.</i> 61:279-293, John Libbet Eurotext (May-June 2003)				
AT	4	Wade, A. and Weller, P.J., eds., "Benzalkonium Chloride," "Benzethonium Chloride," "Cetrimide," in: <i>Handbook of Pharmaceutical Excipients</i> , American Pharmaceutical Association, Washington, DC, pp.27-31, 96-98 (1994)				

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			FIRST NAMED INVENTOR Geall, A.	FILING DATE December 2, 2003
			ART UNIT 1645	

U.S. PATENT DOCUMENTS

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	AA						
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	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AR	5	Copy of Co-Pending U.S. Patent Application No. 09/478,457, Wolff et al., filed January 6, 2000 (NOT PUBLISHED)				
AS	5	Molina, M.C. et al., "Maintenance of nonviral vector particle size during the freezing step of the lyophilization process is insufficient for preservation of activity: insight from other structural indicators." <i>J. Pharma. Sci.</i> 90:1445-1455, Wiley-Liss, Inc (October 2001)				
AT	5	Cherng, J.Y., "Stabilization of polymer-based gene delivery systems." <i>Int. J. Pharma.</i> 183:25-28, Elsevier B.V. (June 1999)				

EXAMINER	DATE CONSIDERED
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